AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q91867

Application No.: 10/562,013

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the

application:

LISTING OF CLAIMS:

Claim 1 (currently amended): A method for the preparation of crystalline

dexloxiglumide by crystallization of the crude product from solvent, characterized in that

isopropyl ether is used as solvent, wherein the crystallization step is performed by adding a

seeding of microcrystalline dexloxiglumide having an average particle size $(D_{50}) \le 20 \mu m$ to a

supersaturated solution of crude dexloxiglumide.

Claim 2 (original): A method according to Claim 1, characterized in that a ratio of one

part by weight of crude product with a quantity of between 1.5 and 3 parts by volume of

isopropyl ether solvent is used.

Claim 3 (canceled).

Claim 4 (currently amended): A method according to Claim 3 Claim 1, characterized in

that the seeding is added to a supersaturated solution of crude dexloxiglumide which is kept at a

temperature of between 35 and 40°C, in a ratio of one part of seeding material to 40-200 parts of

crude product.

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Claim 5 (currently amended): A method according to Claim 3 Claim 1, characterized in

that, wherein after the addition of the seeding material, the reaction mass is stirred at a

temperature of between from 34 and to 38°C, preferably 36°C, for a period of between from 2

and to 8 h, preferably 6 h, and the temperature of the reaction mass is then reduced slowly, with

stirring, to 10 ± 5°C over a period of between from 6 and to 10 h, preferably 8 h, and in which

wherein the crystallized solid is recovered by filtration.

Claim 6 (original): Dexloxiglumide in crystalline particle form having a percentage (by

volume) of less than 15% of fine particles having dimensions less than 10 $\mu m,$ and an average

particle size value (D_{50}) of between 50 and 130 μm .

Claim 7 (original): Dexloxiglumide according to Claim 6 in crystalline particle form,

having an average particle size value (D50) of between 80 and 100 $\mu m.$

Claim 8 (previously presented): Dexloxiglumide in crystalline particle form according

to Claim 6, having a particle-size distribution with a span index of less than 2.5.

Claim 9 (previously presented): Dexloxiglumide according to Claim 6, obtainable by

means of a method of preparation by crystallization.

Claim 10 (previously presented): A pharmaceutical composition for oral use

comprising, as active substance, dexloxiglumide according to Claim 6.

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Claim 11 (original): A pharmaceutical composition according to Claim 10, comprising dexloxiglumide in a quantity of between 50 and 500 mg and optional pharmaceutically acceptable vehicles.

Claim 12 (original): A pharmaceutical composition according to Claim 11, comprising, as inactive ingredients, pharmaceutically acceptable vehicles selected from diluents, disaggregants, lubricants, flow-promoting agents, and mixtures thereof.

Claim 13 (original): A pharmaceutical composition according to Claim 12, comprising, as vehicles, substances selected from the group which consists of starch, microcrystalline cellulose, sodium glycolate, tale, magnesium stearate, silicon dioxide, and mixtures thereof.

Claim 14 (previously presented): A pharmaceutical composition for oral use according to Claim 10 for use in the treatment of diseases of the digestive tract, particularly of irritable colon syndrome, non-ulcerative dyspepsia, biliary colic and dyskinesia, gastro-oesophageal reflux, pancreatitis, and gastrointestinal motility disorders.